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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO.          |
|--|-------------|----------------------|-------------------------|---------------------------|
| 10/508,445   | 09/16/2004  | Joseph P Orban III   | 2786                    | 6710                      |
| 7590   | 04/20/2006  |                      |                         | EXAMINER<br>ROY, ANURADHA |
| Kimberly V Perry<br>U.S. Surgical a division of<br>Tyco Healthcare Group<br>150 Glover Avenue<br>Norwalk, CT 06856 |             |                      | ART UNIT<br>3736        | PAPER NUMBER              |
|  |             |                      | DATE MAILED: 04/20/2006 |                           |

Please find below and/or attached an Office communication concerning this application or proceeding.

| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|------------------------------|------------------------|---------------------|--|
|                              | 10/508,445             | ORBAN, JOSEPH P     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Anuradha Roy           | 3736                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 16 September 2004.

2a)  This action is FINAL.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-32 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1-32 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/20/04.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

Claim 29 is objected to because of the following informalities: Claim 29, a apparatus claim, is dependent on claim 27, a method claim. For purposes of examination, Examiner has made the assumption that its dependency is on claim 28, rather than 27. Appropriate correction is required.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the tube (Claim 2) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-9, 12-16, 18-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Cochran et al. (US Patent No. 5,215,521).

Regarding claims 1 & 19, Cochran et al. discloses a tissue removal device and method, comprising:

an elongate shaft (Figure 4, shaft of 26) having a distal end and a proximal end, wherein the elongate shaft defines a longitudinal axis;

a bag support (26) defining an opening, the bag support being collapsible and expandable to open and close the opening;

a bag (22) operatively attached to the bag support, the bag having an open first end operatively secured to the bag support and a closed end, the first end being connected to the support so that when the bag support is in the collapsed position the bag opening is substantially closed; and

the bag (22) inherently capable of having folds including at least one transverse fold.

Regarding claim 2, Cochran et al. discloses a tissue removal device further comprising a tube (16) for receiving the shaft, bag support and bag.

Regarding claim 3, Cochran et al. discloses a tissue removal device wherein the folds are capable of having folds approximately parallel with the longitudinal axis (Figure 3).

In regards to claim 4, Cochran et al. discloses a tissue removal device, further including a sheath (20) disposed about the bag assembly.

Regarding claim 5, Cochran et al. discloses a tissue removal device, wherein the sheath is inherently capable of having a weakness for breaking away from the bag. It is noted that the sheath is made of “a plastic construction” (Column 9, line 42).

With regard to claim 7, Cochran et al. discloses a tissue removal device, wherein the sheath is inherently in the form of at least one of a mesh, net and lattice. It is noted that a solid is inherently made up of a lattice, which is “a regular geometrical arrangement of points or objects over an area or in space” ([www.webster.com](http://www.webster.com), © 2002 Merriam-Webster, Inc).

Regarding claim 8, Cochran et al. discloses tissue removal device, further comprising an actuation system (16, 18, 21, 24) operatively connected to the sheath in order to facilitate removal of the sheath from the bag assembly (Column 10, lines 28-35).

In regards to claim 9, Cochran et al. discloses a tissue removal device, wherein the actuation system (16, 18, 21, 24) includes a tear line (21, Column 10 lines 1-5 & 28-35) formed in the sheath to facilitate tearing of the sheath.

Regarding claim 12, Cochran et al. discloses a tissue removal device, wherein the actuation system includes an expandable member (24 & 26) positioned within the bag assembly.

With regard to claim 13, tissue removal device, wherein expansion of the expandable member (24) is initiated remotely from the bag.

In regards to claim 14, Cochran et al. discloses a tissue removal device, wherein the bag (22) has a proximal edge and a distal edge and includes a slot (Figure 4) formed in the vicinity of the bag support near the proximal edge to enable the diameter of the bag to be adjusted.

Regarding claim 15, Cochran et al. discloses a tissue removal device, wherein the bag includes a control line (26) for drawing the slot closed.

With regard to claim 16, Cochran et al. discloses a tissue removal device, wherein the bag is conical in shape (Figure 4).

With regard to claim 18, Cochran et al. discloses a tissue removal device, further comprising a control portion (18, 20, 21, 21, 24) operatively coupled to the proximal end of the shaft.

With regard to claim 20, Cochran et al. discloses a method, wherein the bag is folded onto itself such that the proximal edge is inherently capable of crosses the distal edge (Figure 3).

In regards to claim 21, Cochran et al. discloses a method further comprising folding the bag so that the folds are approximately parallel to the longitudinal axis (Figure 3).

Regarding claim 22, Cochran et al. discloses a method, wherein the bag support has a collapsed position (Figure 3) and an expanded position (Figure 4) and further comprising closing the upper end of the bag using the support (26).

In regards to claim 23, Cochran et al. discloses a method, wherein the bag is folded onto itself such that the proximal terminal edge of the bag is substantially parallel with the longitudinal axis (Figure 3).

With regard to claim 24, Cochran et al. discloses a method, wherein the bag is folded onto itself such that the proximal terminal edge of the bag is substantially aligned with the longitudinal axis (Figure 3).

Regarding claim 25, Cochran et al. discloses a method, wherein the bag is folded so that a portion of the bag is disposed distally of a distal end of the support (Figure 3).

In regards to claim 26, Cochran et al. discloses a method, further comprising the step of placing the folded bag and bag structure into a sheath (Figure 3).

In regards to claim 27, Cochran et al. discloses a method, wherein the sheath inherently includes a weakness and further comprising tearing the sheath at the weakness so as to release the bag (Column 10, lines 1-5 & 28-25).

Regarding claim 28, minimally invasive tissue removal device for passage through a cannula, the device comprising:

an elongate shaft (Figure 4, shaft of 26) having a distal end portion and a proximal end portion, the elongate shaft defining a longitudinal axis;

a bag assembly (22 & 26) operatively coupled to the distal end portion of the shaft, the bag assembly including:

a bag support (26) structure having a first position and a second position; and  
a bag (22) having an upper end and a lower end, the upper end having an open position and a closed position and being operatively secured to the bag support such that when the bag support is in the first position, the upper end of the bag is substantially open (Figure 4) and when the bag support is in the second position, the upper end of the bag is substantially closed (Figure 3);

the bag is inherently capable of being folded over onto itself so as to form a transverse fold (Figure 3).

Regarding claim 29, Cochran et al. discloses a tissue removal device, further comprising a removable sheath (22) disposed about the bag assembly when in the bag is in the folded condition (Figure 3).

Regarding claim 30, Cochran et al. discloses a tissue removal device according, wherein the bag has a proximal edge and a distal edge (Figure 4) and wherein the bag is capable of being folded such that the proximal edge is substantially aligned with the longitudinal axis (Figure 3).

Regarding claim 31, Cochran et al. discloses a minimally invasive tissue removal device for passage through a trocar, the device comprising:

an elongate shaft (Figure 4, shaft of 26) having a distal end portion and a proximal end portion, the elongate shaft defining a longitudinal axis;

a bag support (26) at the distal end of the shaft having a first position (Figure 3) and a second position (Figure 4), the bag defining a plane in the first position;

and a bag (22) having an open end and a closed end opposite the open end (Figure 4), the bag extending along a bag axis which is perpendicular to the longitudinal axis (Figure 4), the bag having an open position and a closed position (Figures 3&4);

wherein the bag is capable of being folded over onto itself such that the bag axis is oriented substantially parallel to the longitudinal axis of the shaft (Figure 3).

With regard to claim 32, Cochran et al. discloses a tissue removal device, wherein the bag is folded into a cylinder adjacent the bag support (Figure 3).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cochran et al. in view of Summer (US Patent No. 5,899,694).

Cochran et al. discloses a tissue removal device with the aforementioned elements.

However, Cochran et al. does not directly disclose a tissue removal device, wherein the sheath is fabricated from a flexible heat-shrinking polymer. Summer et al., however, discloses a sheath fabricated from a flexible heat-shrinking polymer (18). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Summer to use a flexible heat-shrinking polymer as the sheath material with Cochran et al.'s invention to permits the sleeve to be bent and minimize interference with the procedure, while also capable of remaining straight or assume other shapes, if desired (Column 5, 64-67).

***Additional Claim Rejections - 35 USC § 103***

Claim 10 & 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cochran et al. in view of Snow et al. (US Patent No. 6,402,722).

Cochran et al. discloses a tissue removal system with the above-mentioned elements. However, Cochran et al. does not disclose a device, including a cord operatively connected to the tear line for facilitating the tearing of the sheath along the tear line. Snow et al., however, discloses a cord (18) operatively connected to the tear line for facilitating the tearing of the sheath along the tear line (Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Snow et al. to incorporate a cord with Cochran et al.'s invention in order to remove the sheath.

Snow et al. further discloses a device, wherein the cord is connected to a control portion (16) at the proximal end of the shaft.

***Additional Claim Rejections - 35 USC § 103***

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cochran et al.

Cochran et al. discloses removal device and method comprising: an elongate shaft (Figure 4, shaft of 26), a bag support (26), and a bag (22) conical in shape. However, Cochran et al. does not expressly disclose that the bag can be trapezoidal in shape.

At the time the invention was made, it would have been obvious to one having ordinary skill in the art to make the bag trapezoidal in shape because Applicant has not disclosed that making the bag trapezoidal in shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Cochran et al.'s removal device, and applicant's invention to perform equally well with either the spacing taught by Cochran et al. or the claimed trapezoidal shape because both shapes would perform the same function of retrieving and retaining tissue.

Therefore, it would have been *prima facie* obvious to modify Cochran et al. to obtain the invention specified in claim 17 because such modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Cochran et al.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~



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